Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria® assessment of gravid cervix.

BIBLIOGRAPHIC SOURCE(S)

Angtuaco TL, Gupta N, Andreotti RF, Lee SI, DeJesus Allison SO, Horrow MM, Javitt MC, Lev-Toaff AS, Scoutt LM, Zelop C, Expert Panel on Women's Imaging. ACR Appropriateness Criteria® assessment of gravid cervix. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 5 p. [33 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Fleischer AC, Andreotti RF, Bohm-Velez M, Fishman EK, Horrow MM, Hrocak H, Thurmond A, Zelop C, Expert Panel on Women's Imaging. Premature cervical dilation. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 7 p. [27 references]

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Cervical incompetence

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Obstetrics and Gynecology
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for premature cervical dilatation (cervical incompetence)

TARGET POPULATION

Patients with premature cervical dilatation (cervical incompetence)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Transperineal/transvaginal sonography
2. Digital examination

MAJOR OUTCOMES CONSIDERED

- Utility of radiologic examinations in diagnosis of cervical incompetence
- Incidence of spontaneous midtrimester birth

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by the Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Assessment of Gravid Cervix

Variant 1: Patient not at risk for preterm delivery: 16-24 weeks gestation; cervix <3 cm long or suggestion of funneling by transabdominal ultrasound examination.

Radiologic Procedure	Rating	Comments	RRL*
Ultrasound (US) pregnant uterus (transvaginal or transperineal) report minimum cervical length in mm or cm	9	Assess for cervical change several times over a 10-minute period.	None
US pregnant uterus (transvaginal or transperineal) report endocervical diameter in mm (if no residual cervical length)	9		None
US pregnant uterus (transvaginal or transperineal)	6	Performed only in settings with provisions for labor and delivery.	None

Radiologic Procedure	Rating	Comments	RRL*
cervical stress test			
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Variant 2: Patient at risk for preterm delivery (history of prior preterm birth or multiple gestations): 16-24 weeks gestation: cervix <3 cm long by transabdominal or transvaginal ultrasound examination.

Radiologic Procedure	Rating	Comments	RRL*
Ultrasound (US) pregnant uterus (transvaginal or transperineal) report minimum cervical length in mm or cm	9	Assess for cervical change several times over a 10-minute period.	None
US pregnant uterus (transvaginal or transperineal) report endocervical diameter in mm (if no residual cervical length)	9		None
US pregnant uterus (transvaginal or transperineal) cervical stress test	7	Performed only in settings with provisions for labor and delivery.	None
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Summary of Literature Review

The term *cervical incompetence* was first introduced in 1948 by Palmer and Lacomme. This condition, which is characterized by painless midtrimester cervical dilatation, has a reported incidence of 1% and may be responsible for as many as 20% of second trimester miscarriages.

As a result of recent investigations that recognize features shared by women with cervical incompetence and those with premature labor, the concept of cervical incompetence as an "all or none" phenomenon has been challenged. Cervical

incompetence is believed to represent a continuum that relates to cervical length and pregnancy history.

Regardless of the precise definition for this condition, there is no debate that preterm birth (<37 weeks of gestation) continues as the leading cause of perinatal morbidity and mortality. Consequently, it remains a major obstetrical challenge. Various methods for diagnosing preterm cervical dilatation have been proposed.

Digital Examination

Initial assessment is usually clinical and is based on digital palpation of the cervix. This examination can detect changes in cervical texture such as softening (which occurs as a precursor to delivery), and it can appreciate distensibility of the external os. These findings occur relatively late in the process of cervical dilatation, however, and in some cases are found too late to be reversed. Further, some physicians question the accuracy of digital measurements, which consistently underestimate measurements made by transperineal or transvaginal ultrasound (US). Most likely, this inaccuracy is due to the anatomic configuration of the cervix because the portion of cervix that lies above the anterior fornix or above the bladder base is hidden from the examiner's fingers. The digital examination has other limitations: 1) it is a subjective assessment; 2) the internal cervical os, which reflects initial changes associated with premature cervical dilatation, is beyond the examiner's reach; and 3) there are potential side effects that include risk of infection and ruptured membranes.

Nonetheless, if a patient is clinically at risk for preterm delivery, or if the US examination detects a short cervical length, some obstetrician-gynecologists may perform a digital cervical examination. Once the patient is near term (>37 weeks), and early delivery is no longer an issue, this examination can be omitted, unless clinically indicated for other reasons. To optimize the results and patient management, it is important to correlate the findings of the ultrasound examination with the digital examination.

Sonographic Examination

Unlike digital examination, sonographic measurements of cervical length generates an image that may be reviewed and standardized, thus overcoming subjectivity.

Normal-appearing cervix: During pregnancy, the length of the cervix does not elongate appreciably. Most authorities consider 3.0 cm in length as the lower limit of normal.

Transabdominal evaluation: Although most obstetrical sonographic examinations are done transabdominally, it is the least reliable imaging method for evaluating the cervix. Using this approach, bladder overdistension as well as myometrial contractions can change the appearance of the lower uterine segment and cervix, creating a deceivingly normal appearance in women with cervical effacement, shortening, or frank dilatation. Furthermore, an underdistended bladder may preclude adequate cervical visualization for any one of a variety of reasons: acoustic shadowing from the pubic symphysis, refractive shadowing from the bladder-uterine interface, and loss of the acoustic window provided by the urinary

bladder and/or amniotic fluid, or an inability to manually displace the fetal head or other presenting part superiorly away from the lower uterine segment. Even when visible on a transabdominal scan, the cervical image is usually suboptimal. Because the external os is often not clearly identified, a technically correct cervical length measurement may not be possible. Therefore, if a patient has a clinical history or sonographic findings suspicious for cervical pathology, consideration should be given to cervical scanning using either a transperineal or transvaginal approach.

Transperineal/transvaginal evaluation: These approaches are the most accurate for assessing the cervix, although bladder distension and myometrial contractions may still give a falsely normal cervical appearance. When the cervix is well visualized, transperineal US can predict preterm delivery as accurately as transvaginal US. Cervical length is determined as the distance between the internal and external os. The internal os is normally at the level where the cervical canal meets the amniotic sac. The external os is often more difficult to define precisely because of acoustic shadowing from rectal gas. This problem can be minimized by either scanning the patient in a lateral decubitus position, or by elevating the hips and buttocks on a thick pad or pillow.

In patients at risk for cervical shortening or incompetence, some investigators suggest performing a cervical "stress test" by either applying transfundal pressure while scanning transvaginally, or examining the patient while she is standing. Because some patients will initially have a completely normal-appearing cervix, these important maneuvers may identify additional women who may require treatment for preterm cervical dilatation. If the cervix is already dilated or short, the cervical stress test may not be necessary because it may compound the problem by inducing further dilatation and shortening.

Abnormal-appearing cervix: Although the clinical presentation varies, from an imager's point of view cervical changes are essentially identical in patients in term labor, preterm labor, or cervical incompetence. In each of these clinical situations, cervical dilatation begins proximally, at the level of the internal os, and progresses distally. As the internal os dilates, membranes and amniotic fluid invaginate into the proximal endocervical canal. The most accepted terminology for these changes is *funneling*, although *wedging* or *beaking* have also been used. The disruption of the internal os, as documented by funneling, is a significant risk factor for adverse perinatal outcome. Cervical funneling is best described as a categorical variable (present or absent). In fact in a large series of 1,958 patients, the mean gestational age at delivery was significantly lower in the group with funneling compared with the group without funneling.

Eventually the entire endocervical canal becomes filled with fluid, and if the membranes remain intact, they may be visible bulging into the vagina. Concurrent with dilatation, the cervix becomes effaced and shortened. Dilatation and effacement typically progress simultaneously, although, in a given patient, one or the other event may appear to predominate. Investigators have recommended quantifying these cervical changes using a variety of measuring techniques, but the simplest and most reproducible measurement in sensitivity and predictive value appears to be the residual closed length of cervix. This calculation, which takes into account both dilatation and effacement, can be obtained by measuring from the distal apex of endocervical funneling at the internal os to the external os.

Analysis by one study of low-risk pregnancies studied with transvaginal US indicates that using a cutoff value for cervical length of 33.15 mm yields an 80% sensitivity for predicting preterm delivery. This cutoff value resulted in a 12.7% false positive rate. Another multicenter observational study done for cervical length on transvaginal US from 16 to 24 weeks gestation categorized short cervical lengths as less than 25 mm, 25-29 mm, and 30 mm or greater. In both, the less than 25 mm group and 25-29 mm group, the incidence of spontaneous midtrimester birth (<26 weeks) was higher than the incidence of later (26-34 weeks) preterm birth (<25 mm group: 37% versus 19%; 25-29 mm group: 16% versus 3%, respectively) as compared with women with a longer cervical length of 30 mm or greater, who had rates of 1% and 9% respectively (p<.0001). Similarly, women who had an initial cervical length 30 mm or less and those who shortened their cervix to 30 mm or less before 22 weeks were also more likely to experience a midtrimester than later preterm birth. On the other hand, women whose cervix has shortened to 30 mm or less after 24 weeks or maintained a length greater than 30 mm had lower rates of midtrimester birth (p<.0001).

If a woman is clinically at risk for preterm delivery (such as prior preterm birth and multifetal gestation), or if a short cervix is detected by sonography, the precise length of the cervix should be measured and reported (this measurement is based on transperineal or transvaginal scans). Endocervical canal dilation of 2 to 4 mm during second-trimester endovaginal sonography has been associated with an increased risk of recurrent preterm delivery independent of cervical length. Studies have shown that serial transvaginal surveillance of cervical length in patients followed by cervical cerclage only when cervical changes are encountered appears to reduce the cerclage rate without compromising pregnancy outcome. In addition, in cases with visible dilatation, the sonologist should report the maximal endocervical diameter. The percent of "effacement" based on sonographic images is not reliable, because it is not possible to determine the location of the internal os once dilatation becomes apparent.

False negative diagnoses can occur during transperineal or transvaginal scanning if a cervical stress test is omitted. Some of the most challenging patients to evaluate are those in whom the appearance of the cervix changes during the sonographic examination. These transient but important observations underscore the need to observe the appearance of the cervix several times during a single obstetrical sonographic study, and suggest that a single image of the cervix may be insufficient for thorough cervical evaluation. A study of dynamic cervical change on 10-minute real-time US showed that minimum cervical length was a better predictor of preterm delivery than was initial cervical length. Another study demonstrated that on transvaginal US assessment of cervical length performed at 18, 24, 28 and 32 weeks gestation, shortening of cervical length ≥2.5 mm per week between 18 and 28 weeks' gestation also predicted preterm delivery. This is particularly the case in women at risk for preterm delivery, or those in whom a short cervix is detected by sonography. When a woman has transitory cervical changes, the minimal length of residual cervix should be reported, and the patient should be considered at risk. Clinical follow-up of these women reveals that 61% to 74% have preterm labor or deliver prematurely.

Summary

Transperineal and transvaginal sonography provides unique information about the cervix that is otherwise not readily available. These examinations are easy to perform, have been shown to predict the risk for preterm delivery and, in the appropriate clinical setting, should become an integral part of the obstetrical sonographic study.

Relative Radiation Level	Effective Dose Estimated Range
None	0
Minimal	<0.1 mSv
Low	0.1-1 mSv
Medium	1-10 mSv
High	10-100 mSv

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Transperineal and transvaginal sonography provides unique information about the cervix that is otherwise not readily available. Appropriate selection of radiologic imaging procedures for evaluation and diagnosis of patients with premature cervical dilatation may prevent preterm birth (<37 weeks of gestation).

POTENTIAL HARMS

There is potential for a false diagnosis (false positive) or for a failure to diagnose (false negative) preterm cervical dilatation during transperineal or transvaginal scanning.

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included

for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see "Availability of Companion Documents" field).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Angtuaco TL, Gupta N, Andreotti RF, Lee SI, DeJesus Allison SO, Horrow MM, Javitt MC, Lev-Toaff AS, Scoutt LM, Zelop C, Expert Panel on Women's Imaging. ACR Appropriateness Criteria® assessment of gravid cervix. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 5 p. [33 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 (revised 2008)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Women's Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Teresita L. Angtuaco, MD; Nidhi Gupta, MD; Rochelle F. Andreotti, MD; Susanna I. Lee MD, PhD; Sandra O. DeJesus Allison, MD; Mindy M. Horrow, MD; Marcia C. Javitt, MD; Anna S. Lev-Toaff, MD; Leslie M. Scoutt, MD; Carolyn Zelop, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

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The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® *Anytime*, *Anywhere*™ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.
- ACR Appropriateness Criteria® radiation dose assessment introduction. American College of Radiology. 2 p. Electronic copies: Available from the ACR Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on December 28, 2000. The information was verified by the guideline developer on January 25, 2001. This summary was updated by ECRI Institute on June 15, 2009.

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